K053043

510(k) Summary

NOV 18 2005

Date:	October 7, 2005
Submitter's Name:	Toshiba America Medical Systems, Inc.
Submitter's Address:	P.O. Box 2068, 2441 Michelle Drive, Tustin, CA 92781-2068
Submitter's Contact:	Paul Biggins, Regulatory Affairs Manager (714) 730-5000
Establishment Registration Number:	2020563
Device Proprietary Name:	Software for Encompass **URSE-001A, URFR-001A, URTQ-001A**
Common Name:	Software
Regulatory Class:	**Class II**
Performance Standard:	none
Predicate Device(s):	Agfa Corp. Encompass [K040896], Toshiba SSA-770A [K041499], General Electric Vivid 7 with TSI [K031663]
Reason For Submission	new device (software)

Description of this Device:

These software packages are to be applied to the imaging processing system Encompass from Agfa Corp. Using the software listed to post-process images, various analysis and reconstruction can be initiated by the user to obtain clinically relevant information pertaining to cardiac and radiology. Additionally this information can be used in the detection of cardiovascular disease and radiology diagnosis and risk management. Support functions are:

- **URSE-001A**: Stress Echo analysis of the ultrasound diagnostic images.
- **URFR-001A:** Three-dimensional image reconstruction from the ultrasound diagnostic images for abdominal, small organs and peripheral vascular.
- **URTQ-001A** : Following analysis from the TDI (Tissue Doppler Image) from the ultrasound diagnostic images.
  - Gray scale (display of only black-and-white images)
  - Velocity display (display of the velocity after angle correction and smoothing)

- Display of the velocity gradient based on the velocity image
- Display of the degree of myocardial strain based on the velocity image
- Display of the displacement based on the velocity image
- Display of the dyssynchrony imaging based on the above imaging methods

Summary of Intended Uses:

The software that can be used with the imaging processing system Encompass enables to provide images for the stress echo, to reconstruct three dimensional images for radiology examination and to provide images of TDI (Tissue Doppler Imaging) for cardiac diagnosis.

Technological Characteristics:

These software are similar in uses and applications as those of the predicate devices.

Safety and Effectiveness Concerns:

This device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and the imaging processing system Encompass comply with Underwriters Laboratories (U.L.) Standard No.544 for Medical and Dental Equipment.

Substantial Equivalence:

The software URSE-001A, URFR-001A and URTQ-001A is substantially equivalent to the predicate devices, Agfa Corp. Encompass [K040896], Toshiba SSA-770A [K041499], General Electric Vivid 7 with TSI [K031663].

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 8 2005

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re.: K053043
Trade/Device Name: Encompass Software Package
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system.
Regulatory Class: II
Product Code: LLZ
Dated: October 26, 2005
Received: October 28, 2005

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053043

Device Name: Software for Encompass (Model Numbers: URSE-001A, URFR-001A, URTQ-001A)

Indications for Use:

Using the software listed to post-process images, various analysis and reconstruction can be initiated by the user to obtain clinically relevant information pertaining to cardiac and radiology. Additionally this information can be used in the detection of cardiovascular disease and radiology diagnosis and risk management. Support functions are:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053043